

- Amended B3*
- b) oleic acid or a salt thereof, or palmitoyl oleoyl phosphatidylglycerol (POPG) or a salt thereof as a stabiliser, and
 - c) ethanol

wherein the weight ratio of active agent to stabiliser is from 400:1 to 10:1.--

REMARKS

As a preliminary matter, Applicants note that the Examiner has not considered Applicants' Information Disclosure Statement ("IDS") dated August 12, 1998. It appears that the Examiner did not consider the IDS because copies of some or all of the cited references were not received by the Examiner. Applicants enclose herewith a copy of their postcard receipt showing that eight references were in fact submitted with the IDS. Applicants also point out that the remaining references need not be submitted to the Patent Office because the remaining references were cited in the international stage search report which is present in the instant application (i.e., "the national stage application") with its annexes as indicated by Form PCT/DO/EO/903 mailed by the Patent Office December 3, 1998. MPEP § 609 states in part that

[t]he Examiner will consider the documents cited in the international search report in a PCT national stage application when the Form PCT/DO/EO/903 indicates that both the international search report and the copies of the documents are present in the national stage file."

See MPEP § 609, page 600-103. Thus, Applicants' IDS did in fact comply with the relevant rules, and the IDS should have been considered.

For the Examiner's convenience, however, Applicants provide with this Response another copy of the IDS in question, along with a copy of every reference cited therein. Applicants respectfully request that the Examiner consider the IDS and the references in their entirety, and that the Examiner sign and initial the PTO Form 1449 to reflect his efforts in this regard.

In claims 1-4, Applicants are claiming a concentrate that comprises a particular cyclosporin, ethanol as solvent; and a stabilizer selected from oleic acid or a salt thereof, or POPG or a salt thereof, wherein the concentrate is free of poly(oxyethylene)-40 (POE-40) castor oil and wherein the weight ratio of cyclosporin to stabilizer is from 400:1 to 10:1. In claim 5, Applicants claim an emulsion comprising the concentrate of claim 1 and a placebo fat emulsion.

Initially, Applicants respectfully submit that claim 5 is not a substantial duplicate of claim 1, in that claim 5 is limited to an emulsion. While the concentrate of claim 1 is used in preparing the